4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; Notice of

Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public

advisory committee of the Food and Drug Administration (FDA).

The meeting will be open to the public.

Name of Committee: Advisory Committee for

Pharmaceutical Science.

General Function of the Committee: To provide advice

and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 7 and 8,

2002, from 8:30 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research

Advisory Committee Conference Room, rm. 1066, 5630 Fishers

Lane, Rockville, MD.

Contact Person: Kathleen Reedy or Jayne Peterson, Center

for Drug Evaluation and Research (HFD-21), Food and Drug

Administration, 5600 Fishers Lane (for express delivery, 5630

Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001,

or e-mail REEDYK@cder.fda.gov, or PETERSONJ@cder.fda.gov, or

FDA Advisory Committee Information Line, 1-800-741-8138

(301-443-0572 in the Washington, DC area), code 12539.

Please call the Information Line for up-to-date information

on this meeting.

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Agenda: On May 7, 2002, the committee will: (1) Discuss the current status of, and future plans for, the draft FDA guidance entitled "Guidance for Industry, Food-Effect Bioavailability and Fed Bioequivalence Studies: Study Design, Data Analysis, and Labeling" (see the FDA Internet address www.fda.gov/cder/guidance/4613dft.PDF under "Biopharmaceutics (Draft) Guidances"); (2) discuss and provide comments on the biopharmaceutic classification system; and (3) discuss and provide direction for future subcommittees. On May 8, 2002, the committee will: (1) Receive summary reports and provide direction for the Process Analytical Technology Subcommittee; (2) discuss and provide comments on regulatory issues related to crystal habits-polymorphism; (3) discuss problems and provide comments to form a scientific basis for establishment of acceptance limits for microbiological tests that use newly developed technologies that do not rely on colony counts and their application as process controls and product release criteria; and (4) discuss the current status of, and future plans for, the draft FDA guidance entitled "Guidance for Industry, ANDAs: Blend Uniformity Analysis" (see FDA Internet address www.fda.gov/cder/guidance/2882dft.PDF under "Generics (Draft) Guidances").
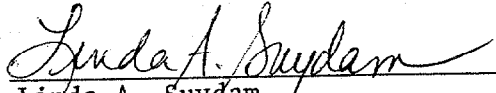
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 26, 2002. Oral presentations from the public will be scheduled between approximately 11:30 a.m. to 12:30 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 26, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kathleen Reedy or Jayne Peterson at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal
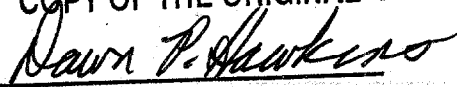
Advisory Committee Act (5 U.S.C., app. 2).

Dated _4/11/02_____.
April 11, 2002.

Linda A. Suydam
Linda A. Suydam
Senior Associate Commissioner for
Communications and Constituent Relations.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Dawn P. Hawkins